

TECHNOLOGY TRANSFER UNIVERSITY OUTLINE
6610 Rockledge Drive, Room 4033

Day One (May 3, 2006)

Morning -- Patents

Bruce Goldstein, Office of Technology Transfer, OD

What is “IP,” and briefly identify differences between the four types

Patents

What is a patent, determining ownership, and rights of patent owners

What kinds of inventions are patentable

Criteria for patentability

Statutory subject matter

Utility

Novelty

Non-obviousness

Written description (incl: “constructive reduction to practice”)

PHS policy on patenting and licensing

Exercise: cases involving inventions

Afternoon -- Other Types of Intellectual Property

Bruce Goldstein

Copyrights

What items can be copyrighted

Determining ownership

Rights of © owners

Trademarks

What marks are eligible to be trademarks

Rights of TM owners

Trade Secrets

What information can be protected as a trade secret

Rights of T/S owners

PHS policy on each type of non-patent IP

Exercise: Identify the applicable IP for each project

Day Two: (May 10, 2006)

Morning -- Patent Process

Steve Marquis, NCI

Process for acquiring a patent in the United States
General process for acquiring a patent in other countries (Patent Cooperation Treaty)
IC responsibilities throughout the process, using NCI procedures as an example

Afternoon -- Laws Pertinent to Tech. Transfer

Dale Berkley, Office of General Council

Primer: What really is “law”?
Differences between constitution, statute, EO, regulation, policy
Relationship between legislative codes and judicial cases
Federalism -- interplay of federal and state laws

For each of the following laws, the history, content, and implications to NIH:
Bayh-Dole
Stevenson-Wydler,
EO 10096, and 37 CFR Part 404
FTTA and NTTAA (“Morella Bill”)
AIPA and CREATE Act
FOIA and OMB Circular A-110
Anti-deficiency/Adequacy of Appropriations acts
various false-statements-to-government and the Federal Trade Secrets acts

Day Three (May 17, 2006)

Morning – Tech. Transfer Agreements

Laurie Whitney, NCI

Overview of Agreements: Types of agreements; when to use each type

Confidential Disclosures and Material Transfers:

- Definition of “confidential information” and exclusions

- (In)appropriate restrictions on disclosure

- PHS policy on publication

- Duration of obligations

- Issues raised by category of materials being transferred

- Ownership vs mere possession

- Transfers of materials vs transfers of IP embodied by materials

- (In)appropriate uses of materials

- Redistribution and disposal

- Reach-through and other IP issues

Afternoon -- CRADAs

Kathleen Carroll, NCI

- Key components and organization of CRADAs

- Conflict of interest

- NIH review/approval process

- Research plans

- Contribution of resources

- Statutory licenses

- Key clauses

Day Four (May 24, 2006)

All Day - Clinical Trial Issues

Suzanne Frisbie, NCI

How to address human subject issues in tech. transfer agreements.
Laws and regulations relevant to the conduct of clinical trials and human subject use (including Hatch-Waxman, orphan drugs, IRB regulations, etc.)
The FDA's approval process for drugs, biologics, and devices (CDER, CBER, and CDRH)
Distribution of responsibilities among the parties involved
Institutional Review Boards (IRBs)
Use of human tissues separate from a clinical trial
Intramural versus extramural clinical trials
INDs (including types of sponsorship and DMFs)
Combination studies
Trade-secrets
Ethical considerations such as DSMBs, Informed Consents, drug supply, confidentiality, ADE reports, and use of data.

Day Five (May 31, 2006)

Morning -- Licenses to Patentable Technologies

Sue Ano, Office of Technology Transfer, OD

Overview – Licensing at OTT

Authorities for Licensing

Types of PHS licenses, and procedures for each type of license

Case Studies:

- Royalty types

- License scope, development plans, and key milestones

- Sublicensing and license-transfer issues

- Retained rights/licenses

- Collection, termination, & enforcement/litigation

- Marketing strategies

NIH royalty administration

Afternoon – Customer Service and Negotiation Techniques

Karen Maurey, NCI

Identifying who is the “customer” of tech-transfer services

How to handle various common situations in negotiations

Tools for improving communications and for recovering from mistakes

Wrap-up negotiation exercise